REMARKS/ARGUMENTS

Reconsideration and allowance in view of the foregoing amendment and the following remarks are respectfully requested.

Claims 1-9 and 11-26 are now pending.

The Examiner objected that the Information Disclosure Statement filed March 7, 2002 allegedly fails to comply with Rules 97 and 98 because the lined through reference does not have a date.

Reconsideration of the Examiner's refusal to consider the "Spectral Flatness" publication is respectfully requested. In this regard it is respectfully submitted that it is not uncommon for an undated document to be cited and supplied in an Information Disclosure Statement. Sometimes the Examiner will annotate the listing with "(no date)", but it is respectfully submitted that it is not a prerequisite for information consideration for the information to bear a date. To do so would penalize an applicant that is fulfilling their duty to disclose by submitting a document simply because, for some reason outside the control of the applicant, the document bears no date. This is certainly not the intent of the provisions the Examiner has cited. Just like the author need only be listed if the author is identified in a publication, the date is not required if it is unknown and the document does not include a date. It is therefore respectfully submitted that the listing of the "Spectral Flatness" document was as complete as possible and because the submission of a copy of that document and its listing were timely, the document should be considered by the Examiner even though it does not bear a date. It is noted in this regard that the document is also listed on page 3 of applicant's disclosure.

For all the reasons advanced above, it is respectfully requested that the Examiner now acknowledge consideration of the timely cited and supplied "Spectral

Flatness" article. Because the Examiner defaced the original Form PTO-1449, a fresh Form PTO-1449 bearing the same listing is supplied herewith.

The disclosure was objected to because of noted informalities. The specification has been reviewed and revised in view of the Examiner's comments. It is believed that the informalities noted by the Examiner have all been corrected.

The claims were objected to as including noted informalities. The claims have been reviewed and revised to correct the matters noted by the Examiner. Reconsideration and withdrawal of the objection is requested.

Claims 1-14 were rejected under 35 USC 112, second paragraph, as being indefinite. The claims have been reviewed and revised to address the maters noted by the Examiner. It is believed that the claims are now in full compliance with 35 USC 112, all paragraphs, and it is therefore respectfully requested that the rejection be withdrawn.

Original claims 1-4, and 6-14 were rejected under 35 USC 102(b) as being anticipated by Brown et al. Applicant respectfully traverses this rejection.

The object of Brown is to avoid delivery of unsuccessful defibrillator countershock: Brown discloses a system wherein a patient in cardiac arrest is subject to ECG analysis, in particular FFT analysis of the VF signal. The objective of the analysis is to extract one or more features of the FFT or time domain signal which characterize the metabolic condition of the heart. This information can be displayed, or can be used to determine proper treatment. A fundamental property of Brown is the comparison of the calculated information with given thresholds and, based on that comparison, determine if a countershock should be given or if other interventions should continue until the desired threshold is reached. One preferred embodiment of this technology is within a defibrillator. Suggested further applications include:

* Determine myocardial perfusion and metabolic state

* Control a resuscitator
* Optimize CPR characteristics, real time with a resuscitator. The characteristics found optimal with a resuscitator can then potentially be used as recommendations for manual CPR.
* Control characteristics of defibrillator therapy
* Control drug delivery

Brown claims that the information can be continuously sampled to obtain the value of Fc and/or Fp, at column 5, line 6. This is not supported, however, by the example, column 7, line 30 - 49, where it is disclosed that only 128 of a total of 324 segments could be analyzed. The rest could not be analyzed because of artifacts from cardiopulmonary resuscitation or other noise. Applicant respectfully submits that this is a serious limitation of the Brown system, because only the proposed embodiment where a resuscitator is controlled by the technology may avoid signal analysis during CPR. Another limitation of the Brown system is disclosed in the flowchart of Figure 2. Here, a patient can only be defibrillated when the Fc and/or Fp has reached a pre-defined threshold. This threshold is suggested to have a range, and the range suggested is exactly the range found in table 1 for successful countershock outcome. However, looking at table 3, which is successful admission to hospital, the value ranges of Fc and Fp respectively extend significantly beyond the desired values, indicating that a number of patients can have survival to hospital admission if they were defibrillated at lower thresholds than the recommendation by Brown. In other words, Brown's method may reduce the number of unsuccessful countershocks, but at the cost of losing patients that otherwise would have been admitted alive.

Anticipation under Section 102 of the Patent Act requires that a prior art reference disclose every claim element of the claimed invention. See, e.g., Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1574 (Fed. Cir. 1986). While other references may be used to interpret an allegedly anticipating reference, anticipation must be found in a single reference. See, e.g., Studiengesellschaft Kohle,

G.m.b.H. v. Dart Indus., Inc., 726 F.2d 724, 726-27 (Fed. Cir. 1984). The absence of any element of the claim from the cited reference negates anticipation. See, e.g., Structural Rubber Prods. Co. v. Park Rubber Co., 749 F.2d 707, 715 (Fed. Cir. 1984). Anticipation is not shown even if the differences between the claims and the prior art reference are insubstantial and the missing elements could be supplied by the knowledge of one skilled in the art. See, e.g., Structural Rubber Prods., 749 F.2d at 716-17.

Claim 1 has been amended hereinabove so as to incorporate the fact that both magnitude and rate of change are compared with earlier data when the decision support is produced. This provides a significant improvement in the decision support. Amended claim 1 also makes it clear that both CPR and ECG signals are measured and used in the comparison. A new independent claim 15 has been added to define the invention in a slightly different manner but is also based on the rate of change and magnitude.

The present invention differs from the Brown '424 disclosure in several respects. A system is described by applicants which is arranged to calculate the probability of ROSC, Prosc, based on measured characteristic of the patient's ECG, and to calculate the development of the probability figure, DProsc. The purpose is to use Prosc information to support the decision on further treatment. Furthermore the invention includes sensors to measure CPR performance, where the system also provides feedback to instruct the user in effective CPR, to provide automatic decision support on the question of whether or not to give CPR, and in which way CPR should be given. Furthermore, the invention is arranged to track the development of the probability figure, in order to identify effective manual CPR. Positive changes in Prosc may identify certain characteristics of CPR which are effective. Neutral or negative changes in Prosc indicate that the ongoing effort is not effective. For instance, if CPR does not counter the natural degradation of Prosc over time, CPR should discontinue. In case the therapy does not allow Prosc to improve sufficiently, a time limitation is implemented to

allow defibrillator therapy even for lower values of Prosc. To further improve the precision of Prosc, it is possible to input patient information. Because the information in VF can be extracted in several ways, the present invention list optimized filter banks, wavelets and neural networks as useful tools for information extraction. The system may further be arranged with an impedance measurement system capable of measuring a signal which represents the amount of blood coming from the heart. A significant difference is the method of establishing generality (general applicability); that the decision criteria for which a countershock is recommended is not optimized for a small sample of patients, but valid for a broad range of patients. A further significant difference is the availability of CPR sensor information. Because it is generally accepted that CPR creates artifacts, the information from the CPR sensors can be used to allow pROSC calculations while CPR is not performed.

On page 12, of the Examiner's Official Action, the Examiner concludes that Brown discloses an analysis unit which identifies periods of positive changes in the probability figure. Applicant respectfully disagrees, because Brown discloses a system where the present value is compared with a predefined threshold. The rate of change does not influence the flowchart in Figure 2 thereof, nor is the rate of change characterized in tables 1-4. Applicant also respectfully disagrees with the Examiner's characterization of the Brown display unit in Figure 3 as being a receiver of a numerical value of a positive change in the probability figure, because there is no mention in the description that such a change is calculated. Applicants also respectfully disagree with the Examiner's conclusion that Brown discloses a receiver of a numerical value of a positive change in the probability figure together with a mean value of each treatment parameter, again because Brown does not utilize the rate of change of his parameters. Applicants also respectfully disagree with the Examiner's characterization of Figures 1 - 2 as indicating the possibility of indicating/inputting patient specific information.

In view of the foregoing, reconsideration and withdrawal of the Examiner's rejection based on Brown is solicited.

Claims 1-3, 6, 8, 10 and 14 were rejected under 35 USC 102(b) as being anticipated by Selker et al. Applicant respectfully traverses this rejection.

Selker discloses a system to monitor the medical condition of a patient, with the purpose of calculating a probability of a medical outcome or diagnosis based on the monitored features. Selker includes means to input patient specific information. However, the invention of Selker itself is not relevant to applicant's claimed invention other than it points to specific methods and technology as prior art. Specifically, that Selker measures ECG, that a probability figure is calculated based on algorithms, and that the receiver is arranged for decision support.

As noted above, claim 1 has been amended hereinabove so as to incorporate the fact that both magnitude and rate of change are compared with earlier data when the decision support is produced. This is not described in Selker and provides a significant improvement in the decision support. Amended claim 1 also makes it clear that both CPR and ECG signals are measured and used in the comparison.

All objections and rejections having been addressed, it is respectfully submitted that the present application is in condition for allowance and an early Notice to that effect is earnestly solicited.

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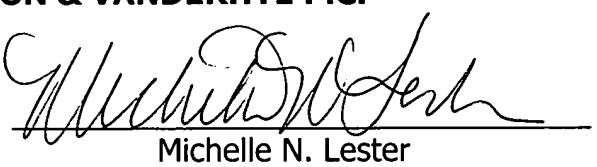
Respectfully submitted,

NIXON & VANDERHYE P.C.

By: 

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